BlueCross BlueShield Federal Employee Program

SUTENT (sunitinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Sutent (sunitinib malate) is a small molecule inhibitor of multiple membrane-bound and intracellular kinases involved in normal cellular functions and in pathologic processes such as oncogenesis, tumor angiogenesis, and maintenance of the tumor microenvironment (1).

Regulatory Status

FDA-approved indications: Sutent is a kinase inhibitor indicated for the treatment of adult patients with: (1)

1. Gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate
2. Advanced renal cell carcinoma (RCC)
3. Adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy
4. Progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease

Off-Label Uses: (2-5)

1. Recurrent chordoma
2. Relapsed or unresectable renal cell carcinoma
3. Neuroendocrine tumors
    a. Unresectable
    b. Metastatic disease
4. Soft tissue sarcoma
    a. Angiosarcoma
    b. Solitary fibrous tumor
    c. Hemangiopericytoma
    d. Alveolar Soft Part Sarcoma (ASPS)
5. Papillary, Hurthle Cell, or Follicular thyroid carcinoma
    a. Unresectable recurrent or persistent
    b. Distant metastatic disease
6. Medullary thyroid carcinoma
    a. Progressive disease
    b. Symptomatic distant metastatic disease

7. Thymic carcinoma

Sutent carries a boxed warning for severe and sometimes fatal hepatotoxicity. Liver function tests (ALT, AST, and bilirubin) should be monitored at baseline, during each cycle, and as clinically indicated. Sutent should be interrupted or discontinued based on the grade of hepatotoxicity (1).

The safety and effectiveness of Sutent have not been established in pediatric patients (1).

Summary

Sutent (sunitinib) is a kinase inhibitor, designed to block enzymes that promote cancer growth. Sutent has been approved to treat gastrointestinal stromal tumors (GIST), renal cell carcinoma (RCC) and neuroendocrine tumors. Sutent is also used off-label for the treatment of soft tissue sarcoma, thyroid carcinoma, thymic carcinoma and recurrent chordoma. Sutent carries a boxed warning for severe and sometimes fatal hepatotoxicity. Liver function tests should be obtained before initiation of Sutent, and it should be monitored during each cycle and as clinically indicated. The safety and effectiveness of Sutent have not been established in pediatric patients (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Sutent while maintaining optimal therapeutic outcomes.

References

1. Sutent [package insert]. New York, NY; Pfizer Inc.; August 2021.
2. NCCN Drugs & Biologics Compendium® Sunitinib 2025. National Comprehensive Cancer Network, Inc. Accessed on Janaury 14, 2025.
3. NCCN Clinical Practice Guidelines in Oncology® Neuroendocrine and Adrenal Tumors (Version 3.2024). National Comprehensive Cancer Network, Inc. January 2025. Accessed on January 14, 2025.
4. NCCN Clinical Practice Guidelines in Oncology® Soft Tissue Sarcoma (Version 4.2024). National Comprehensive Cancer Network, Inc. November 2024. Accessed on January 14, 2025.
5. NCCN Clinical Practice Guidelines in Oncology® Thymomas and Thymic carcinomas (Version 1.2025). National Comprehensive Cancer Network, Inc. October 2024. Accessed on January 14, 2025.